

September 28, 1998

## **NOTICE TO HHS CERTIFIED AND APPLICANT LABORATORIES**

### **Subject: Guidance for Reporting Specimen Validity Test Results**

The Mandatory Guidelines for Federal Workplace Drug Testing Programs published in the **Federal Register** on June 9, 1994 (59 FR 29908) and the Department of Transportation (DOT) regulations (49 CFR Part 40) applicable to DOT federally regulated programs permit laboratories to conduct additional tests to determine the validity of a specimen. To ensure maximum consistency, the following guidance is provided for all laboratories in determining the validity of a specimen. We have consulted with the Department of Transportation. It agrees with these procedures and definitions and recommends that such procedures be followed for its federally regulated programs.

#### **A. Single and/or Primary (Bottle A) Specimens**

##### **1. Guidance**

- a. A laboratory may determine for each specimen (i.e., from either a single specimen collection or the primary specimen (Bottle A) from a split specimen collection) the nitrite concentration, creatinine concentration, specific gravity, and pH. These tests shall follow scientifically suitable methods and produce results which are accurately quantified.
- b. When a laboratory suspects the presence of an interfering substance/adulterant that could make a specimen unsuitable for testing and the laboratory is unable to identify the interfering substance/adulterant (e.g., glutaraldehyde, surfactant, bleach), the laboratory may send the specimen to another HHS certified laboratory that has the capability of conducting scientifically suitable validity tests to identify the interfering substance/adulterant.
- c. A laboratory shall make every effort to conserve the specimen volume for possible future testing.

##### **2. Definitions**

Based on information gathered from a review of current clinical and forensic toxicology literature and recommendations made by the Substance Abuse and Mental Health Services Administration's Drug Testing Advisory Board, a specimen is defined to be:

- a. *Dilute* if the creatinine is  $< 20$  mg/dL and the specific gravity is  $< 1.003$ , unless the criteria for a *substituted specimen* are met.
- b. *Substituted* (i.e., the specimen does not exhibit the clinical signs or characteristics associated with normal human urine) if the creatinine concentration is  $\leq 5$  mg/dL and the specific gravity is  $\leq 1.001$  or  $\geq 1.020$ .
- c. *Adulterated* if the nitrite concentration is  $\geq 500$   $\mu\text{g/mL}$ .
- d. *Adulterated* if the pH is  $\leq 3$  or  $\geq 11$ .
- e. *Adulterated* if an exogenous substance (i.e., a substance which is not a normal constituent of urine) or an endogenous substance at a higher concentration than normal physiological concentration is present in the specimen.

### 3. Reporting Results

The Federal custody and control form (CCF) requires laboratories to report drug test results as either Negative, Positive (for a specific drug), or Test Not Performed. Additionally, the laboratory must include an appropriate comment on the "Remarks" line in Step 7 on the CCF when the specimen is dilute, adulterated, substituted, or not tested for drugs (e.g., presence of a fatal flaw or uncorrected flaw). If the additional comments cannot be fully described on the "Remarks" line, the laboratory may attach a separate sheet describing the problem, and reference the attachment on the "Remarks" line.

*Note: NLCP Program Document #009 (dated October 10, 1991) and DOT memorandum (dated June 1, 1992) titled "Operating Guidance for DOT Mandated Drug Testing Programs" provide recommendations for rejecting specimens for testing if procedural errors occur.*

The following guidance is provided to report a specimen as Negative, Positive, or Test Not Performed:

**Negative.** The “Negative” box in Step 7 on the CCF is checked when a negative drug test result is obtained on the initial test or on the confirmatory test. If the specimen is also dilute, the laboratory includes the following statement on the “Remarks” line: “Dilute Specimen.”

*Note: A negative drug test result is not reported when the specimen has been determined to be adulterated or substituted.*

**Positive.** The “Positive” and the specific drug/drug metabolite(s) boxes in Step 7 on the CCF are checked when a positive drug test result is obtained on an initial test and a confirmatory test. If the specimen is also dilute, the laboratory includes the following statement on the “Remarks” line: “Dilute Specimen.”

*Note: A positive drug test result is not reported when the specimen has been determined to be adulterated or substituted; however, the laboratory may conduct and complete the confirmatory test.*

**Test Not Performed.** The “Test Not Performed” box is checked in Step 7 on the CCF if the specimen is (1) not tested because of a fatal flaw (e.g., broken seal; specimen ID numbers do not match), (2) not tested because of an uncorrected flaw (e.g., a collector’s signature was omitted and a signed statement is not received to correct the error), (3) unsuitable for testing or contains an unidentified interferant because a valid drug test result cannot be obtained, (4) adulterated, or (5) substituted.

*Note: The “Test Not Performed” box is checked regardless of whether there is a negative or positive drug test result if a specimen has been determined to be adulterated or substituted.*

If the “Test Not Performed” box in Step 7 on the CCF is checked, one of the following statements is to be included on the “Remarks” line:

1. “Fatal Flaw, \_\_\_\_\_” (with the flaw stated)
2. “Uncorrected Flaw, \_\_\_\_\_” (with the flaw stated)
3. “Specimen Unsuitable: Cannot obtain valid drug test result”
- 4a. “Specimen Adulterated: Nitrite is too high”
- 4b. “Specimen Adulterated: pH is too high (or too low)”
- 4c. “Specimen Adulterated: Presence of \_\_\_\_\_ (specify) detected”
5. “Specimen Substituted: Not consistent with normal human urine”

*Note: The quantitative results for validity tests (e.g., nitrite concentration, creatinine concentration, actual specific gravity, or actual pH) may not be routinely*

*reported to the MRO, but may be provided to the MRO upon request on a case by case basis.*

## **B. Split (Bottle B) Specimens**

### **1. Guidance**

- a. When a donor requests, through the MRO, to have the split (Bottle B) specimen tested, a second laboratory (Laboratory B) tests the split specimen for the drug/drug metabolite detected in the primary specimen.
- b. If Laboratory B is unable to reconfirm the presence of the drug/drug metabolite that was reported positive in the primary specimen by Laboratory A, Laboratory B must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug/drug metabolite. Laboratory B should conduct the same validity tests as it would conduct on a primary (Bottle A) specimen.

*Note: Occasionally, Laboratory B is unable to reconfirm the presence of a drug/drug metabolite (i.e., the confirmatory test results fail to satisfy the criteria established by Laboratory B to report a positive test result) but the laboratory believes that the drug/drug metabolite is present. In this case, Laboratory B may decide to continue testing the split specimen in an attempt to get a valid confirmatory test result. If it appears that Laboratory B may possibly use the entire split specimen in an attempt to get a valid confirmatory test result, Laboratory B must contact the MRO and explain the problem. Laboratory B and the MRO must decide if the remaining amount of the split specimen should be sent to a Laboratory C for the confirmatory test. If the decision is made to use a Laboratory C, Laboratory B sends the split specimen using chain of custody procedures to Laboratory C without reporting a result to the MRO.*

- c. If Laboratory B is unable to conduct the validity tests, Laboratory B must send the split (Bottle B) specimen and Copy 3 of the Federal custody and control form using chain of custody procedures to a third laboratory (Laboratory C) that has the capability to conduct the validity tests. If the validity tests conducted by Laboratory C do not determine the reason for being unable to reconfirm the presence of the drug/drug metabolite in the split specimen, Laboratory C must test the split (Bottle B) specimen for the drug/metabolite found in Bottle A by Laboratory A.

## 2. Definitions

Same definitions as in section A.2 of this Program Document.

## 3. Reporting Split Specimen Results

The CCF requires laboratories to report split (Bottle B) specimen test results as either Reconfirmed (notating the specific drug), Failed to Reconfirm, or Test Not Performed. Additionally, the laboratory must include an appropriate comment on the "Remarks" line in Step 7 on Copy 3 of the CCF if it finds that the specimen is adulterated or substituted, or when a drug test was not performed.

The following guidance is provided to report a specimen as Reconfirmed, Failed to Reconfirm, or Test Not Performed:

**Reconfirmed.** The "Reconfirmed" and the specific drug/drug metabolite boxes are checked in Step 7 on Copy 3 when the laboratory confirms the presence of the drug/drug metabolite that was reported positive in the primary specimen.

**Failed to Reconfirm.** The "Failed to Reconfirm" box in Step 7 on Copy 3 of the CCF is checked if (1) the drug/drug metabolite is not detected, (2) the specimen is adulterated, or (3) the specimen is substituted.

If the "Failed to Reconfirm" box is checked, one of the following statements must be included on the "Remarks" line:

1. "Drug/Drug metabolite not detected"
- 2a. "Specimen Adulterated: Nitrite is too high"
- 2b. "Specimen Adulterated: pH is too high (or too low)"
- 2c. "Specimen Adulterated: Presence of \_\_\_\_\_ (specify) detected"
3. "Specimen Substituted: Not consistent with normal human urine"

**Test Not Performed.** The "Test Not Performed" box in Step 7 on Copy 3 of the CCF is checked if (1) the specimen is not tested for drugs or (2) the testing could not be completed successfully.

If the "Test Not Performed" box is checked, one of the following statements must be included on the "Remarks" line:

- 1a. "Fatal Flaw, \_\_\_\_\_ (with the flaw stated)"
- 1b. "Uncorrected flaw, \_\_\_\_\_ (with the flaw stated)"
- 2a. "Specimen Unsuitable: Cannot obtain valid confirmatory test result"

2b. "Insufficient specimen volume to complete testing"

This Program Document supersedes and replaces PD #033, and should be used in conjunction with DOT memorandum ("MRO Guidance for Interpreting Specimen Validity Test Results") dated September 28, 1998.

If you have any questions regarding this guidance, please contact my staff at (301) 443-6014.

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